Amendments to the Drawings:

The Office Action objected to the drawings because of non-uniform line width, and because reference character 22 has been used to designate both the RF heat source and the tip of the device 21. The above amendment to the paragraph bridging pages 7 and 8 of the specification overcomes the objection based on reference character 22.

Replacement Drawing Sheets 1 and 2 are enclosed herewith. Please replace the original drawing sheets 1 and 2 with these new sheets.

## REMARKS/ARGUMENTS

Claims 11-19 and 21-28 are pending. Claims 11-28 were objected to because of various minor informalities. Claims 11 and 18 were rejected under 35 U.S.C. 112, second paragraph. Claims 11-14, 16-18, and 20-28 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,662,108 to Budd et al. Claims 15 and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Budd et al.

The specification and drawings were also objected to because of various minor informalities.

Applicant has amended the specification to correct the matters noted by the Examiner. Corrected drawings are also enclosed herewith to address the drawing objections.

Response to Rejections Under 35 U.S.C. 102(b)

The Budd et al. reference relied upon in the Office Action is concerned with a device for mapping a human heart. The present invention relates instead to an apparatus used for human bladder mapping. Because there are fundamental differences between the human heart and the human bladder physically, and in terms of the way they behave, a heart-mapping apparatus such as disclosed by Budd would be unsuitable for mapping a human bladder. This is explained below.

The heart has a largely constant volume and is full of fluid at all times. Furthermore, electrical activity occurs continually as the heart beats, and thus there is no need to take any particular actions to "prod" the heart into manifesting electrical activity. In contrast, the human bladder is a passive organ that can change volume significantly over time, and much of the time there is little electrical activity. Thus, in order to *stimulate* electrical activity so that it can be detected during a test procedure, it is advantageous to fill the bladder with a sterile fluid so that it is distended (see specification at page 8, lines 6-9). It requires a significant volume of fluid (say, at least 300 to 500 ml) to fill the bladder adequately for this purpose.

Accordingly, the apparatus in accordance with Claim 11 as amended includes a filling lumen adapted to permit passage of a sterile fluid from the exterior through the filling lumen into the bladder for distending the bladder.

Budd's apparatus does not include any such filling lumen, nor would there be any reason or motivation to add one to Budd's apparatus[1]. Indeed, it would be inadvisable to include a filling lumen open to the heart from the exterior. First, it would never be necessary to supply a substantial volume of fluid into a heart (which of course beats during this procedure, and is completely full of liquid anyway). Furthermore, an open lumen would add significantly to the volume of the heart, and may have unintended medical effects.

With respect to Claim 20, the Office Action asserted that Budd's balloon catheter 94 includes a fluid lumen to permit filling of the bladder, because "filling of balloon 96 Figure 3 would also fill the organ that the bladder (sic, balloon) is placed in". However, Budd's balloon 96 would have much too small a volume to be effective at causing the degree of distension required for a human bladder to evoke the desired electrical activity—i.e., since the balloon would never be inflated to fully fill the heart ( because the heart would cease to function properly), it is hardly likely to be expandable to fill a (much larger) human bladder. Furthermore, bladder expansion caused by an artificial balloon would not replicate the effects of

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[1] Some prior art heart catheter devices include an open guide wire lumen. A stiff guide wire is inserted first into the patient (typically through the femoral artery), and using an imaging system the guide wire is advanced up into the desired region of the heart. A catheter device or lumen then is inserted over the guide wire so as to be guided to the desired location, after which the guide wire is withdrawn. This leaves an open lumen, which is typically closed by a valve outside the body. The guide wire is typically 1 mm or less in diameter, and the lumen is not much bigger, because there is no point in making it bigger than it need be. However, the volume required (say, 300-500 ml minimum) to distend a human bladder could not be passed through such a small-diameter lumen in any sensible time frame, particularly in view of the fact that in a heart catheter, the guide wire lumen is long (up to 1000 mm) because the catheter is typically inserted through the femoral artery in the upper thigh region. It would be extremely difficult to force a significant volume of fluid through such a long and narrow passage. In contrast, a filling lumen for the bladder would be short (say, 300 mm) and of a much larger diameter capable of allowing quick filling so as to minimize the intervention period and discomfort of the patient.

Sometimes a narrow lumen, which might be of guide wire lumen size, is used to infuse a small volume of contrast media into the heart so that operation of the heart valves can be imaged. This small volume diffuses in the blood quickly, and in any event is very small in relation to heart volume.

filling by fluid, because the tendency of a balloon is to maintain a balloon shape, whereas a human bladder will likely expand rather asymmetrically with fluid. The purpose of the claimed invention is to measure actual bladder performance parameters, so artificial expansion by balloon is not likely to replicate real-life conditions, and thus permit defects to be detected and treated. In any event, the filling lumen of the claimed invention is for filling the *human* bladder, not the inflatable bladder.

Additionally, Budd's lumen used for inflating the balloon 96 is not "adapted to permit passage of a sterile fluid from the exterior *through an open end of the filling lumen into the bladder* for distending the bladder" as claimed. The end of Budd's lumen is by necessity *closed* in order to be able to inflate the balloon 96.

Thus, Budd does not anticipate Claim 11 (and hence does not anticipate any of dependent Claims 12-19 and 21-28).

Response to Rejections Under 35 U.S.C. 103(a)

The basis of the rejections of Claims 15 and 19 under 35 U.S.C. 103(a) is that Budd discloses the apparatus according to Claims 14 and 18, and further discloses the additional limitations in Claims 15 and 19. For the above-noted reasons, however, Claims 14 and 18 are not anticipated by Budd.

Therefore, the rejections under 35 U.S.C. 103(a) are improper because Budd fails to disclose all of the limitations of Claims 15 and 19. In particular, as noted, Budd fails to disclose a bladder-mapping apparatus having a filling lumen as claimed.

Conclusion

Based on the above amendments and remarks, it is submitted that all claims are patentable over Budd and the application is in condition for allowance.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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